

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES INC.,)	
GALDERMA LABORATORIES, L.P. and)	
SUPERNUS PHARMACEUTICALS, INC.,)	
)	
Plaintiffs,)	C.A. No. 11-1106 (LPS)
)	
v.)	
)	REDACTED -
AMNEAL PHARMACEUTICALS, LLC. and)	PUBLIC VERSION
AMNEAL PHARMACEUTICALS CO. (I))	
PVT. LTD.,)	
)	
Defendants.)	

PROPOSED JOINT PRETRIAL ORDER

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On May 7, 2014, counsel for Plaintiffs¹ and Amneal² will participate in a pretrial conference before this Court pursuant to Rule 16 of the Federal Rules of Civil Procedure, Local Rule 16.3, and this Court's March 13, 2014 Oral Order (D.I. 212). Pursuant to Local Rule 16.3, Plaintiffs and Amneal hereby submit for the Court's approval this proposed Joint Pretrial Order governing the bench trial of Civil Action No. 11-1106-LPS, which is currently scheduled to begin on June 2, 2014.

Plaintiffs are represented by: Gerald J. Flattmann, Jr. (geraldflattmann@paulhastings.com), Gregory A. Morris (gregorymorris@paulhastings.com), and Evan D. Diamond (evandiamond@paulhastings.com) of Paul Hastings LLP, 75 East 55th Street, New York, NY 10022, 212-318-6000, and Jack B. Blumenfeld (jblumenfeld@mnat.com) and Maryellen Noreika (mnoreika@mnat.com) of Morris, Nichols, Arsht & Tunnell LLP, 1201 North Market Street, P.O. Box 1347, Wilmington, DE 19899, 302-658-9200.

Amneal is represented by H. Keeto Sabharwal (keetos@skgf.com), Paul A. Ainsworth (painsworth@skgf.com), Jonathan Tuminaro (jtuminar@skgf.com), and Dennies Varughese (dvarughe@skgf.com) of Sterne, Kessler, Goldstein & Fox PLLC, 1100 New York Avenue, NW, Washington, DC 20005, 202-772-8511, and Mary B. Matterer (mmatterer@morrisjames.com) and Kenneth L. Dorsney (kdorsney@morrisjames.com) of Morris James LLP, 500 Delaware Avenue, Suite 1500, Wilmington, DE 19801, 302-888-6800.

This Order shall control the subsequent course of this action, unless modified by the Court to prevent manifest injustice.

¹ "Plaintiffs" when used hereinafter with reference to C.A. No. 11-1106-LPS, shall mean the Plaintiffs in that action, namely Galderma Laboratories Inc., Galderma Laboratories, L.P., and Supernus Pharmaceuticals, Inc.

² "Amneal," when used hereinafter with reference to C.A. No. 11-1106-LPS shall mean Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals Co. (I) Pvt. Ltd.

I. Nature of the Case – Civil Action No. 11-1106-LPS

A. Nature of the Action

1. This is an action for patent infringement brought pursuant to the Hatch-Waxman Act, codified as amended at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), concerning the drug Oracea[®], approved by the Food and Drug Administration for the treatment of the papules and pustules of rosacea.

B. Plaintiffs' Complaints

2. On November 8, 2011, Plaintiffs brought suit against Amneal for infringement of three patents – U.S. Patent Nos. 7,749,532 (“the ‘532 patent”), 7,232,572 (“the ‘572 patent”), and 7,211,267 (“the ‘267 patent”) – based on Amneal’s filing of Abbreviated New Drug Application (“ANDA”) No. 203-278 and accompanying certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV certification”) that it intended to manufacture, sell or offer for sale its generic version of Oracea[®] prior to the expiration of those patents. In their Complaint, Plaintiffs alleged that Amneal infringed, and/or contributed to, aided and abetted, and/or induced infringement of the ‘532 patent pursuant to 35 U.S.C. § 271(e)(2)(A) by submission of its ANDA and accompanying Paragraph IV certification. Plaintiffs further alleged that Amneal would infringe, contribute to or induce infringement if Amneal were to sell, offer for sale, manufacture, or import the products described in ANDA No. 203-278.

3. On July 24, 2012, Plaintiffs filed a First Supplemental Complaint against Amneal (D.I. 74) to include a claim for infringement of U.S. Patent No. 8,206,740 (“the ‘740 patent”) based on Amneal’s filing of ANDA No. 203-278. In their First Supplemental Complaint, Plaintiffs repeated all allegations from their original Complaint and also alleged that Amneal infringed, and/or contributed to, aided and abetted, and/or induced infringement of the ‘740

patent pursuant to 35 U.S.C. § 271(e)(2)(A) by submission of its ANDA. Plaintiffs further alleged that Amneal would infringe, contribute to or induce infringement if Amneal were to sell, offer for sale, manufacture, or import the products described in ANDA No. 203-278.

4. On October 12, 2012, Plaintiffs filed a Second Supplemental Complaint against Amneal (D.I. 128), which removed the ‘572 patent and the ‘267 patent from the case, and repeated Plaintiffs’ infringement allegations with respect to the ‘532 and ‘740 patents.

5. In their Second Supplemental Complaint (D.I. 128), Plaintiffs sought judgment that: (a) Amneal had infringed the ‘532 patent and the ‘740 patent; (b) pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Amneal’s ANDA No. 203-278 be no earlier than the expiration of the ‘532 and the ‘740 patents, including any extensions; (c) Amneal, its officers, agents, servants and employees and those persons in active concert or participation with any of them, be enjoined from commercially manufacturing, using, offering to sell, selling, or importing any products described in ANDA No. 203-278 prior to the expiration of the ‘532 and the ‘740 patents, including any extensions; (d) Plaintiffs be awarded the attorneys’ fees, costs, and expenses they incur in prosecuting this action; and (e) Plaintiffs be awarded such other and further relief as this Court deems proper.

6. Plaintiffs are asserting against Amneal claims 1-8 and 15-21 of the ‘532 patent; and claims 1, 2, 6-15, and 19-22 of the ‘740 patent.

C. Amneal’s Answers and Counterclaims

7. Amneal filed its First Answer and Counterclaims on January 30, 2012 (D.I. 12). Then, on June 6, 2012, Amneal filed its First Amended Answer and Counterclaims in connection with its Motion for Partial Judgment on the Pleadings based on Collateral Estoppel (D.I. 52)

regarding the ‘572 and ‘267 patents. The Court granted Amneal’s motion (D.I. 104) and entered judgment of noninfringement in Amneal’s favor on the ‘572 and ‘267 patents.

8. On August 10, 2012, Amneal filed its Answer and Counterclaims to Plaintiffs’ First Supplemental Complaint. On October 26, 2012, Amneal filed its Answer and Counterclaims to Plaintiffs’ Second Supplemental Complaint. Amneal’s Answer to the Second Supplemental Complaint asserted defenses that each of the remaining patents-in-suit -- the ‘532 and ‘740 patents -- are invalid and not infringed, and that Plaintiffs’ allegations fail to state a claim upon which relief can be granted. Amneal also alleged counterclaims for a declaration of noninfringement of the ‘532 patent and the ‘740 patent and a declaration of invalidity of the ‘532 patent and the ‘740 patent.

9. In its Answer and Counterclaims to the Second Supplemental Complaint, Amneal sought judgment that: (a) dismisses the Complaint with prejudice; (b) declares that the commercial manufacture, use, sale, offer for sale, marketing, or importation of Amneal’s ANDA product does not infringe any valid claim of the ‘532 or ‘740 patents; (c) declares that the claims of the ‘532 and ‘740 patents are invalid; (d) enjoins Plaintiffs, their officers, employees, agents, representatives, attorneys, and others acting on its behalf, from threatening or initiating infringement litigation against Amneal or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Amneal, or charging them either orally or in writing with infringement of any patent asserted against Amneal; (e) declares this an exceptional case under 35 U.S.C. § 285 and awards Amneal its costs and attorneys’ fees; and (f) awards Amneal such other and further relief as the Court may deem proper.

D. Plaintiffs' Answer to Amneal's Counterclaims

10. On November 12, 2012, Plaintiffs filed their Answer to Amneal's Counterclaim to the Second Supplemental Complaint (D.I. 152), denying that Amneal was entitled to any relief as asserted in its Counterclaims or otherwise.

E. Amneal's Amended Answer and Counterclaims

11. Amneal moved for leave to file an amended Answer and Counterclaims on January 10, 2013, and the Court granted that motion on September 30, 2013 (D.I. 191). Amneal filed its Amended Answer, Affirmative Defenses, and Counterclaims to the Second Supplemental Complaint on October 2, 2013 (D.I. 192). Amneal's Amended Answer, Affirmative Defenses, and Counterclaims to the Second Supplemental Complaint alleged additional counterclaims for a declaration of unenforceability due to inequitable conduct, a declaration that Plaintiffs be barred from asserting the '740 patent against Amneal due to unclean hands, and a declaration of breach of contract.

12. In addition to the judgment sought in its Answer and Counterclaims to the Second Supplemental Complaint, Amneal in its Amended Counterclaims also sought judgment that: (a) declares the claims of the '532 and '740 patents unenforceable; and (b) declares that Plaintiffs are barred from asserting the claims of the '740 patent against Amneal.

F. Plaintiffs' Answer to Amneal's Amended Counterclaims

13. On October 21, 2013, Plaintiffs filed their Answer to Amneal's Amended Counterclaim to the Second Supplemental Complaint (D.I. 201), denying that Amneal was entitled to any relief as asserted in its Amended Counterclaims or otherwise.

G. Pending Motions

14. There are presently no pending motions in this action.

II. Jurisdiction

15. Civil Action No. 11-1106-LPS is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271, *et seq.* This Court has subject matter jurisdiction over these actions under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper under 28 U.S.C. §§ 1391(c) and 1400(b). Jurisdiction and venue are not disputed.

III. Facts

A. Uncontested Facts

16. The parties' statement of uncontested facts is set forth in Exhibit 1.

17. These uncontested facts require no proof at trial and are part of the evidentiary record in the case.

B. Contested Facts

18. Plaintiffs' statement of issues of fact that they contend remain to be litigated is attached as Exhibit 2.

19. Amneal's statement of issues of fact that it contends remain to be litigated is attached as Exhibit 3.

20. Should the Court determine that any issue identified in a party's statement of contested issues of fact to be litigated is more properly considered an issue of law, it should be so considered.

IV. Issues of Law

21. Plaintiffs' statement of issues of law that they contend remain to be litigated is attached as Exhibit 4.

22. Amneal's statement of issues of law that it contends remain to be litigated is attached as Exhibit 5.

23. Should the Court determine that any issue identified in a party's statement of issues of law that it contends remain to be litigated is more properly considered an issue of fact, it should be so considered.

V. Witnesses

A. Witnesses to Be Called

24. Plaintiffs' list of the names and addresses of witnesses that they intend to call at trial is set forth in Exhibit 6.

25. Amneal's list of the names and addresses of witnesses that it intends to call at trial is set forth in Exhibit 7.

26. The parties' lists of witnesses indicate which witnesses they currently intend to call and which witnesses they may call to testify at trial. This list also indicates whether a party intends to introduce live testimony or deposition testimony for each witness. With the exception of witnesses to provide foundation as provided in paragraph 27, any witness not listed will be precluded from testifying absent good cause shown.

27. The parties reserve the right to call additional witnesses to provide foundation testimony should any party contest the authenticity or admissibility of any material proffered at trial.

28. **PLAINTIFFS' VERSION:** Presentation of evidence will follow the burden of proof, except that any expert witness may testify regarding all issues set forth in his or her expert report(s) when first called. Nothing in this paragraph precludes the right of a party to offer rebuttal testimony as appropriate.

AMNEAL'S VERSION: Presentation of evidence will follow the burden of proof. Nothing in this paragraph precludes the right of a party to offer rebuttal testimony as appropriate.

29. The parties agree that expert witnesses need not be sequestered. The parties agree that fact witnesses shall be sequestered.

30. The parties shall identify the witnesses whom they expect to call for direct examination, and the order in which they expect to call said witnesses, by 6:00 p.m. on the day before the direct examination is expected to take place.

31. In the event that a witness who was designated by a party to testify live at trial is not available or otherwise cannot testify live due to unforeseeable circumstances beyond the offering party's control, upon a showing of good cause, the offering party may designate deposition testimony in lieu of live testimony at trial. If a party is permitted by the Court to designate testimony, the opposing party will have reasonable notice and an opportunity to counter-designate deposition testimony.

B. Testimony by Deposition

32. Having exchanged testimony which will be offered by designation of deposition testimony, and having met and conferred in an effort to resolve the objections set forth hereto:

a. Plaintiffs' deposition designations, Amneal's objections and counter-designations to the offered testimony, and Plaintiffs' objections to Amneal's counter-designations are set forth in Exhibit 8.

b. Amneal's deposition designations, Plaintiffs' objections and counter-designations to the offered testimony, and Amneal's objections to Plaintiffs' counter-designations are set forth in Exhibit 9.

c. **PLAINTIFFS' VERSION:** A party may rely on any of the opposing party's deposition designations as counter-designations. For convenience and sake of brevity, the parties have listed counter-designations in response to specific affirmative designations by their opposing parties. To the extent an opposing party withdraws any affirmatively designated testimony or seeks to limit the manner of presentation of testimony through the designation process, a party may present its counter-designation testimony in response to other specified affirmative testimony by the opposing party, or re-designate its counter-designated testimony affirmatively.

AMNEAL'S VERSION: [*Omit "Plaintiffs' Version Paragraph 32(c)"*]

33. Subject to instruction from the Court regarding whether deposition testimony shall be read or played in open court or submitted to the Court via an annotated transcript showing the designated deposition testimony, counter-designations, and unresolved objections, the following provisions shall apply to deposition testimony the Court desires read or played in open Court:

a. If a party designates deposition testimony, and the other party counter-designates, the designations and counter-designations will be read or played in chronological order. Regardless of whether deposition testimony is read or played in open court or submitted to the Court via an annotated transcript, the time available for each party's trial presentation shall be reduced by the length of its designations and counter-designations.

b. **PLAINTIFFS' VERSION:** To the extent any party wishes to narrow the scope of any deposition testimony herein designated, the party shall provide notice of the revised designations to the other party by May 26, 2014. The receiving party shall provide

any narrowing of its counter-designations by May 29, 2014. And the parties shall meet and confer on May 30, 2014 in an effort to resolve any outstanding objections.

AMNEAL'S VERSION: To the extent any party wishes to narrow the scope of any deposition testimony herein designated, the party shall provide notice of the revised designations to the other party no later than 6:00 PM the day before the testimony is to be read or played in court. The receiving party shall provide any narrowing of its counter-designations by 10:00 PM on that day. And the parties shall meet and confer by 11:00 PM on that day in an effort to resolve any outstanding objections.

c. All irrelevant and redundant material, including colloquy between counsel and objections, will be eliminated when the deposition is read or viewed at trial.

VI. Exhibits

A. Exhibits

34. Plaintiffs' list of exhibits that they intend to offer at trial, except demonstrative exhibits and exhibits to be used solely for impeachment, and Amneal's objections to Plaintiffs' exhibits, except objections as to the accuracy of translations, are attached as Exhibit 10.

35. Amneal's list of exhibits that it intends to offer at trial, except demonstrative exhibits and exhibits to be used solely for impeachment, and Plaintiffs' objections to Amneal's exhibits, except objections as to the accuracy of translations, are attached as Exhibit 11.

36. Plaintiffs' trial exhibits will be identified with PTX numbers, starting at PTX 1. Amneal's trial exhibits will be identified with DTX numbers, starting at DTX 1000.

37. Subject to the remaining provisions of this Order, no party may use an exhibit not present on its exhibit list (other than for purposes of impeachment), unless the Court determines that good cause has been shown.

38. Any party may use an exhibit that is listed on the other party's exhibit list, to the same effect as though it were on its own exhibit list, subject to all evidentiary objections. Any exhibit, once admitted at trial, may be used equally by any party, subject to the Federal Rules of Evidence. The listing of a document on a party's list is not an admission that such document is relevant or admissible when offered by the opposing party for the purpose that the opposing party wishes to admit the document.

39. Legible photocopies of U.S. Patents No. 7,749,532 and 8,206,740 and their respective file histories and assignment documents are admissible into evidence, in lieu of certified copies thereof.

40. Legible photocopies of United States patents and the contents of the United States Patent and Trademark Office file histories and assignment documents may be offered and received in evidence in lieu of certified copies thereof, subject to all other objections which might be made to the admissibility of such certified copies.

41. Any trial exhibit that is a document produced by a party in discovery that on its face appears to have been obtained from the files of a party (or a party's predecessor-in-interest, *e.g.*, Shire Laboratories, Inc. and CollaGenex Pharmaceuticals, Inc.), or appears to be an e-mail that was sent to or received by an employee, officer, or agent of a party, shall be deemed *prima facie* to be authentic, subject to the right of the party against whom such a document is offered to adduce evidence to the contrary.

42. **PLAINTIFFS' VERSION:** Any data that (a) on its face appears to have been provided to a party by Wolters-Kluwer, CAM, or a comparable third party market research service; (b) was previously produced by a party in discovery, marked as an exhibit at a deposition, or is produced on or before April 30, 2014 by way of supplemental, updated

production of documents of the same nature as those previously produced; and (c) is contained or incorporated in a trial or demonstrative exhibit shall be deemed *prima facie* to be authentic, subject to the right of the party against whom such a document is offered to adduce evidence to the contrary.

AMNEAL'S VERSION: [*Omit "Plaintiffs' Version Paragraph 42"*]

43. Any party that intends to offer evidence to rebut *prima facie* authenticity of any trial exhibit must specifically identify its objection to authenticity to the opposing party no later than May 16, 2014.

44. On or before the first day of trial, counsel will deliver to the Courtroom Deputy a completed AO Form 187 exhibit list for each party.

45. The parties shall identify (by witness) the trial exhibits, by exhibit number, that they expect to use on direct examination by 6:00 p.m. the day before the direct examination is expected to take place, and objections will be provided no later than 10:00 p.m. the night before their intended use. The parties shall meet and confer in an attempt to resolve any objections to the trial exhibits that are expected to be used during direct examination.

46. Each party will give notice by 6:00 p.m. one day prior to when it intends to complete the presentation of its evidence in its case-in-chief.

B. Demonstrative Exhibits

47. The parties agree that the demonstrative exhibits the parties intend to use at trial do not need to be included on their respective lists of trial exhibits. Plaintiffs' demonstratives will be identified with PDX numbers. Amneal's demonstratives will be identified with DDX numbers.

48. A party will provide demonstrative exhibits (identified by witness) to be used in connection with direct examination by 6:00 p.m. the day before their intended use, and objections will be provided no later than 10:00 p.m. the night before their intended use. The parties shall meet and confer in an attempt to resolve any objections to the demonstrative exhibits that are expected to be used during direct examination.

49. The party seeking to use a demonstrative exhibit will provide a color representation of the demonstrative to the other side in electronic PDF form. However, for video or animations, the party seeking to use the demonstrative will provide it to the other side on a DVD or CD. For irregularly sized physical exhibits, the party seeking to use the demonstrative will provide the other party a color representation as a color PDF in electronic form as well as 8.5x11 copies of the exhibits.

50. This provision does not apply to demonstratives created during testimony or demonstratives used for cross-examination, neither of which need be provided to the other side in advance of their use. This provision also does not apply to demonstratives consisting solely of reproductions of trial exhibits that contain enlargements or highlighting of text or information.

51. If good faith efforts to resolve objections to demonstrative exhibits fail, the objecting party shall bring its objections to the Court's attention prior to the applicable witness being called to the witness stand.

VII. Damages

52. This case does not involve any claims for damages.

VIII. Motions *in Limine*

53. The parties agree to forgo the filing of motions *in limine* as to issues known as of the date of submission of this Proposed Joint Pre-Trial Order.

IX. Discovery

54. With the exception of the limited additional discovery ordered by the Court (D.I. 200) in connection with Amneal's inequitable conduct, breach of contract, and unclean hands claims as discussed below, each party has completed discovery.

55. Discovery regarding Amneal's newly-allowed claims of Inequitable Conduct, Unclean Hands, and Breach of Contract remain outstanding. On October 18, 2013, the Court ordered the deposition discovery Amneal requested in connection with these claims. This discovery is ordered to be completed by May 7, 2014 (D.I. 212). The Court ordered the parties to submit this Proposed Pretrial Order by April 29, 2014 (D.I. 211). But on November 26, 2013, the Court approved the Parties' Stipulation Regarding Request to Adjourn Trial and Stay Action (D.I. 210), where the parties agreed that, if the case proceeded, the parties would "at Amneal's request, complete the three depositions ordered by the Court in D.I. 200, at a mutually convenient time and location after April 15, 2014, and prior to the final pre-trial conference date ordered by the Court [May 7, 2014]." The last of these depositions – a Rule 30(b)(6) deposition of Plaintiff Supernus – is scheduled for May 1. Accordingly, and consistent with the Court's November 26, 2013 Order, the Parties request permission to supplement this Pretrial Order to include any new facts, witnesses, testimony, or exhibits that may be uncovered in that deposition.

X. Non-Jury Trial

56. This is a non-jury trial.

57. Pursuant to order of the Court, opening post-trial briefing may be filed no later than July 14, 2014, and responsive post-trial briefing may be filed no later than August 4, 2014. Opening post-trial briefing may comprise no more than thirty (30) pages in length, and responsive post-trial briefing may comprise no more than twenty (20) pages in length. The

parties' opening post-trial briefing may address any issue properly presented at trial, regardless of burden of proof.

58. **PLAINTIFFS' VERSION:** In addition to their opening post-trial briefs, each party shall separately file their proposed Findings of Fact, which shall be filed on the same date as the deadline for opening post-trial briefs and comprise no more than forty (40) pages in length. The proposed Findings of Fact, separately stated in numbered paragraphs, shall constitute a detailed listing of the relevant material facts the party believes it has proven, in a simple narrative form.

AMNEAL'S VERSION: In addition to their opening post-trial briefs, each party shall separately file their proposed Findings of Fact and Conclusions of Law, which shall be filed on the same date as the deadline for opening post-trial briefs and comprise no more than fifty (50) pages in length. The proposed Findings of Fact, separately stated in numbered paragraphs, shall constitute a detailed listing of the relevant material facts the party believes it has proven, in a simple narrative form. Any proposed Conclusions of Law shall include supporting citations.

XI. Length of Trial

59. This case is currently set for a five-day bench trial on June 2-6, 2014. The parties and the Court will discuss the length of the trial day and total trial time at the pretrial conference, as set forth in the April 19, 2012 Scheduling Order (D.I. 29) ("The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.").

60. Time will be charged to a party for its opening statement, direct and redirect examinations of witnesses it calls (including by designation), and cross-examination of witnesses called by any other party (including by designation). The Courtroom Deputy will keep a running total of trial time used by counsel.

XII. Amendments of the Pleadings

61. Neither Plaintiffs nor Amneal request any further amendments to the pleadings.

XIII. Settlement Certification

62. The parties hereby certify that they have engaged in a good faith effort to explore resolution of the controversy by settlement. The parties, through their respective counsel, have considered the possibility of settlement.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Regina Murphy

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SO ORDERED this ____ day of _____, 2014.

Honorable Leonard P. Stark
United States District Judge